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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,870	06/02/2004	Mitchell I. Kirschner	P017US-P2	3869
74997	7590	06/30/2009		
KV PHARMACEUTICAL COMPANY			EXAMINER	
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			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			06/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/709,870

Applicant(s)

KIRSCHNER ET AL.

ExaminerJAMES H. ALSTRUM
ACEVEDO**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/21/08.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28 and 30-97 is/are pending in the application.
4a) Of the above claim(s) 30-88 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 28 and 89-97 is/are rejected.
7) ☒ Claim(s) 95 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/9/08
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claims 28 and 30-97 are pending. Applicants cancelled claims 1-27 and 29. Claims 30-88 are withdrawn from consideration as being drawn to a non-elected invention. Claims 89-97 are new. **Claims 28 and 89-97 are under consideration in the instant office action.** Receipt and consideration of Applicants' new IDS (submitted 12/9/2008), amended claim set, amended specification, and remarks/arguments submitted on October 21, 2008 are acknowledged. Applicants are advised that a different Examiner is examining the instant application. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments. Applicants' claim amendments have necessitated new grounds of rejection (e.g. rejections under § 112, 1st and 2nd paragraphs), as set forth below.

Election/Restrictions

The restriction requirement mailed January 10, 2008 is noted, as well as Applicants' election of **Group I (original claims 1-29), drawn to a nutritional supplement**. The restriction requirement of record is maintained at this time and remains FINAL.

This application contains claims 30-88 drawn to an invention nonelected with traverse in the reply filed on January 28, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claims 95 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 95 indicates that the vitamin C explicitly recited in parent claim 28 is comprised of calcium ascorbate, calcium threonate, and combinations thereof. This limitation expands the scope of the term vitamin C, which is art recognized as referring to a single specific compound, L-ascorbic acid (or L-ascorbate).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28 and 89-97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter). The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. Applicants' independent claim 28 has been amended to require the presence of from about 50 mg to about 500 mg of calcium and about 27 mg of iron in addition to the other components recited therein. Calcium is interpreted to as referring to elemental calcium. Iron is interpreted as referring to elemental iron. Applicants' cited support does not provide support for elemental iron or elemental calcium. Thus, Applicants' specification does not provide support for nutritional supplements comprising elemental calcium and elemental iron. Applicants' specification only supports nutritional supplements comprising calcium compounds and iron compounds, in addition to the other components recited in instant claim 28. Thus, Applicants' amendments introduce new matter.

The remaining claims are rejected as depending from a rejected claim.

Response to Arguments

Applicant's arguments with respect to claims 28 and 89-97 have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28 and 89-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the capsule" in line 13. There is insufficient antecedent basis for this limitation in the claim.

Claim 89 recites the limitation "the iron compound" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 90 recites the limitation "the iron compound" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 89 recites the limitation "the iron compound" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 97 recites the limitation "the iron compound" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 95 is internally inconsistent, because vitamin C (i.e. ascorbic acid) cannot logically also be calcium ascorbate, calcium threonate, and combinations thereof. Calcium ascorbate, calcium threonate, and combinations thereof are not the same compound as ascorbic acid.

Claim 96 is confusing, because parent claim 28 refers to calcium (i.e. the element). Thus, it is impossible for elemental calcium to be any of the molecules listed in claim 96.

The remaining claims are rejected as depending from a rejected claim.

Response to Arguments

Applicant's arguments with respect to claims 28 and 89-97 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28 and 89-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yehuda (US Pat. 4,851,431) in view of the acknowledged prior art, Chang et al. (US Pat. 4,874,629), Markham (US Pat. 4,968,716), The Merck Index, GB1342974 and Gordeuk et al. (*Blood*, 1986, 67(3), pp 745-52) (of record) for the reasons of recorded restated below.

Applicant Claims

Applicants claim a nutritional supplement comprising (i) from about 50 to about 500 mg of calcium, (ii) from about 100 mg to about 500 mg of omega-3 essential fatty acid, (iii) about 27 mg of iron, (iv) from about 10 mg to about 300 mg of a linolenic acid compound, a linoleic acid compound, or a combination thereof, (v) about 25 mg of vitamin C, (vi) from about 10 mg to about 150 mg of vitamin B6, (vii) from about 0.5 mg to about 3 mg of folic acid, folate, or a derivative or metabolite thereof, (viii) about 170 IU of vitamin D3, and (ix) about 30 IU of vitamin E, wherein the composition is contained in a soft gelatin capsule.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Yehuda (US Pat. 4,851,431) discloses a composition that can be in the form of gelatin capsules and containing linoleic and linolenic acid, pyridoxine, folic acid, ascorbic acid, calciferol, tocopherol, calcium, iron, arachidonic acid and eicosapentanoic acid (Columns 3-4, Column 5, lines 1-20). Arachidonic acid, eicosapentanoic acid (EPA) and docosahexanoic acid (DHA) are essential fatty acids as acknowledged by Applicants. Yehuda also teaches that the compositions may comprise any of the known vitamins, including folic acid (Vitamin B9), ascorbic acid (vitamin C), tocopherol (vitamin E), calciferol (vitamin D), pyroxidine (vitamin B6), etc., as well as one or more minerals, including calcium and iron (col. 4, line 62 through col. 5, line 10). Yehuda's compositions may also comprise natural or synthetic antioxidants (col. 5, lines 10-12). The compositions may also include additional unsaturated fatty acids (e.g. dihomogamma linolenic acid, eicosapentanoic acids arachidonic acid) (col. 5, lines 13-20).

Chang et al. disclose that eicosapentanoic acid is an omega-3 fatty acid and that fish oils are a source of omega-3 fatty acids which also include docosahexaenoic acid and have high pharmacological and dietary potential (Column 1, lines 20-43). It is disclosed that the stability of fish oils can be further increased by mixing with antioxidants and/or vegetable oils, such as sunflower oil (Column 6, lines 1-13). It is disclosed that fish oils can be contained in soft gelatin capsules (Column 5, line 61).

Markham discloses that the combination of calcium ascorbate with edible salts of L-threonic acid improves the establish and maintenance of high levels of vitamin C in the human body (Column 2, lines 50-68, Column 3, lines 1-28).

The Merck Index discloses that calcium phosphate, tribasic is used therapeutically as a calcium replenisher and that vitamin D3 is bioequivalent to vitamin D2 (calciferol) in humans (Pages 256, 1578, 1579).

GB 1342974 discloses an edible preparation containing lipid material subject to rancidity and an enriching nutritionally available iron source in particulate form, in which the iron-containing particles are encapsulated to overcome the effect of iron on the lipid material (Claim 1).

Gordeuk et al. disclose that carbonyl iron is a safe, effective, well-tolerated and inexpensive therapy for iron deficiency anemia and can decrease accidental iron poisoning in children which has been seen with the use of ferrous salts (Page 751).

*Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)*

The difference between the Yehuda and the claimed invention is that Yehuda does not expressly disclose the use of a soft gelatin capsule, the use of sunflower oil, the use of calcium ascorbate and calcium threonate as a source of Vitamin C, the use of vitamin D3, the use of calcium phosphate, tribasic, and the use of encapsulated iron or carbonyl iron as the source of iron. This deficiency is cured by the teachings of Chang, Markham, the Merck Index, GB 1342974, and Gordeuk.

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

The prior art discloses a composition that can be in the form of gelatin capsules and containing linoleic and linolenic acid, pyridoxine, folic acid, ascorbic acid, calciferol, tocopherol, calcium, iron, arachidonic acid and eicosapentanoic acid (Columns 3-4, Column 5, lines 1-20). The prior art amply suggests the same as the prior art discloses and/or suggests that fish oils can be contained in soft gelatin capsules, that sunflower oil stabilizes fish oils, the combination of calcium ascorbate and calcium threonate increases the bioavailability of vitamin C, that vitamin D3 is bioequivalent to calciferol in humans, that calcium phosphate, tribasic is a source of calcium, that encapsulated iron inhibits rancidity of oils caused by the interaction of iron with said oils and that carbonyl iron is a safe and effective nutritional supplement. As such, one of ordinary skill in the art would have been motivated to modify and/or combine the prior art with the expectation that soft gelatin capsules would be a suitable dosage form for nutritional compositions containing oils and essential fatty acids and that the use of sunflower oil would be effective in stabilizing fish oils which are a source of omega-3 fatty acids and that in the nutritional compositions that calcium ascorbate and calcium threonate would be a suitable source

of vitamin C, that vitamin D3 would be a suitable substitute for calciferol, that calcium phosphate, tribasic would be a suitable source of calcium and that encapsulated iron or carbonyl iron would be a suitable source of iron. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Response to Arguments

Applicant's arguments filed October 21, 2008 have been fully considered but they are not persuasive. Applicants traverse the instant rejection by attacking the references individually and arguing that (1) the cited prior art combination is deficient, because it does not teach specific ratios of linolenic acid to linoleic acid and Yehuda is allegedly limited to the ratios of linolenic acid and linoleic acid exemplified in Example 1, (2) the combined prior art is allegedly deficient because it does not teach how to incorporate iron into a soft gelatin capsule dosage without cross-linking the gelatin, (3) the combined prior art not allegedly lacks the necessary motivation to obtained the claimed nutritional supplement and is allegedly not enabled to obtain said supplement wherein the soft gelatin capsule does not become cross-linked.

The Examiner respectfully disagrees with Applicants' traversal arguments. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding (1), none of the pending claims recite a specific ratio of linolenic acid to linoleic acid. In fact, Applicants' claims do not require the presence of both linolenic acid and linoleic acid in the claimed supplement, but merely indicate that combinations of linolenic acid and linoleic acid are suitable and may be used. Applicants' claims encompass embodiments wherein linolenic acid is present, whereas as linoleic acid is absent, and vice versa. Regarding a ratio of components, the only ratios recited are possible ratios of (linoleic acid, linolenic acid, or combinations thereof) to omega-3 fatty acids recited in dependent claims 92-94. The prior art is silent as to specific ratios of linolenic acid/linoleic acid to omega-3 fatty acid, however, the prior art does explicitly teach the inclusion of omega-3 fatty acids. It would have been within the skill of the ordinary skilled artisan to vary the amount of omega-3 fatty acid to obtain the desired nutritional benefit, absent a showing of unexpected results. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Regarding (2)-(3), Applicants' claims do not appear to recite that the nutritional supplement is in the form of a soft gelatin capsule. Nonetheless, even if the claimed supplement is required to be in the form of a soft gelatin capsule, Applicants' claims do not require that the gelatin is not cross-linked. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the absence

of cross-linking of the gelatin of the capsule) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is also noted that soft gelatin capsules are conventional dosage forms for oil-based compositions, such as those compositions comprising oils (e.g. sunflower oil). Thus, there is ample motivation to prepare nutritional supplements in the form of soft gelatin capsules and the prior art does enable the preparation of nutritional supplements contained within soft gelatin capsules. Applicants' arguments are unpersuasive. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28 and 89-97 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of US Patent No. 6,576,666 (USPN '666), each in view of Yehuda (US Pat. 4,851,431), Chang et al. (US Pat. 4,874,629), Markham (US Pat. 4,968,716), *The Merck Index*, GB1342974 and Gordeuk et al. (*Blood*, 1986, 67(3), pp 745-52) (of record).

Claim 9 of USPN '666 claims a composition that contains a mixture of linoleic, linoleic acid, docosahexaenoic, eicosapentanoic, omega-3 fatty acid, and/or omega-2 fatty acid, vitamin B6, folic acid, calcium, vitamin C, vitamin E to which can be add iron, wherein the composition is in the form of a soft gelatin capsule.

The difference between the claims of USPN '666 and the claimed invention is that the claims of USPN '666 does not expressly recite the use of sunflower oil, vitamin C comprising calcium ascorbate, calcium threonate, and mixtures thereof, the use of calcium phosphate, tribasic, the use of vitamin D3 and the use of encapsulated iron or carbonyl iron as the source of iron. These deficiencies are cured by the cited prior art.

Yehuda (US Pat. 4,851,431) discloses a composition that can be in the form of gelatin capsules and containing linoleic and linolenic acid, pyridoxine, folic acid, ascorbic acid, calciferol, tocopherol, calcium, iron, arachidonic acid and eicosapentanoic acid (Columns 3-4, Column 5, lines 1-20). Arachidonic acid, eicosapentanoic acid (EPA) and docosahexaenoic acid (DHA) are essential fatty acids as acknowledged by Applicants.

Chang et al. disclose that eicosapentanoic acid is an omega-3 fatty acid and that fish oils are a source of omega-3 fatty acids which also include docosahexaenoic acid and have high pharmacological and dietary potential (Column 1, lines 20-43). It is disclosed that the stability of fish oils can be further increased by mixing with antioxidants and/or vegetable oils, such as sunflower oil (Column 6, lines 1-13). It is disclosed that fish oils can be contained in soft gelatin capsules (Column 5, line 61).

Markham discloses that the combination of calcium ascorbate with edible salts of L-threonic acid improves the establish and maintenance of high levels of vitamin C in the human body (Column 2, lines 50-68, Column 3, lines 1-28).

The Merck Index discloses that calcium phosphate, tribasic is used therapeutically as a calcium replenisher and that vitamin D3 is bioequivalent to vitamin D2 (calciferol) in humans (Pages 256, 1578, 1579).

GB 1342974 discloses an edible preparation containing lipid material subject to rancidity and an enriching nutritionally available iron source in particulate form, in which the iron-containing particles are encapsulated to overcome the effect of iron on the lipid material (Claim 1).

Gordeuk et al. disclose that carbonyl iron is a safe, effective, well-tolerated and inexpensive therapy for iron deficiency anemia and can decrease accidental iron poisoning in children which has been seen with the use of ferrous salts (Page 751).

The cited prior art suggests that sunflower oil stabilizes fish oils (Chang), the combination of calcium ascorbate and calcium threonate increases the bioavailability of Vitamin C (Markham), that calciferol can be combined with essential fatty acids (Yehuda) and that

vitamin D3 is bioequivalent to calciferol in humans (Merck), that calcium phosphate tribasic is a source of calcium (Merck), that encapsulated iron inhibits rancidity of oils caused by the interaction of iron with said oils (GB 1342974), and that carbonyl iron is a safe and effective nutritional supplement (Gordeuk). As such, one of ordinary skill in the art would have been motivated to modify and/or combine the prior art with the expectation that that the use of sunflower oil would be effective in stabilizing fish oils which are a source of omega-3 fatty acids and that in the nutritional compositions that calcium ascorbate and calcium threonate would be a suitable source of vitamin C, that vitamin D3 would be a suitable substitute for calciferol, that calcium phosphate, tribasic would be a suitable source of calcium and that encapsulated iron or carbonyl iron would be a suitable source of iron. Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of said US Patent to one ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of said claims and the references.

NOTE: Applicants' did not traverse the instant rejection and have indicated their willingness to file a terminal disclaimer upon the indication of allowable subject matter.

Conclusion

**Claims 28 and 89-87 are rejected. Claims 30-88 are withdrawn from consideration.
Claim 95 is rejected. No claims are allowed.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1616

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner is on a flexible schedule, but can normally be reached on M-F ~10am~5:30 pm, and Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616